UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, Plaintiff, vs. SUPER VAPE'Z LLC, a corporation, and MARCO HOFFMAN, HEYDEE HOFFMAN, and JUDITH A. CRAMER, Defendants.	Case No.: _____ **COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin Super Vape'z, LLC, ("Super Vape'z" or "the company"), a corporation, and Marco Hoffman, Heydee Hoffman, and Judith A. Cramer, individuals (collectively, "Defendants") from violating 21 U.S.C. § 331(k), by causing tobacco products, within the meaning of 21 U.S.C. § 321(rr), to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce.

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Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a), and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

4. Defendant Super Vape'z is a Washington limited liability corporation whose registered agent's address is 10518 South Tacoma Way, Ste C., Lakewood, WA 98499, within the jurisdiction of this court. The company has three locations from which it conducts its tobacco product operations: 17520 Meridian E., Ste D, Puyallup, WA 98375; 10518 South Tacoma Way, Ste C, Lakewood, WA 98499; and 20401 Mountain Highway E., Spanaway, WA 98387.

5. Defendant Marco Hoffman is a co-owner of Super Vape'z and the company's registered agent. Mr. Hoffman is responsible for purchasing the company's raw ingredients and materials for shipment directly to the company's Puyallup location.

6. Defendant Heydee Hoffman is Marco Hoffman's wife and the other co-owner of Super Vape'z. She and Mr. Hoffman are the most responsible individuals at the company.

7. Defendant Judith A. Cramer is the General Manager of Super Vape'z. She is in charge of the company's retail operations, including managing inventory and delivering e-liquid products between the company's locations. Defendant Cramer is the most responsible individual at the company when Defendant Marco Hoffman is not present.

8. Defendants Marco Hoffman, Heydee Hoffman, and Cramer have all taken actions to further the company's operations within the jurisdiction of this Court.

Defendants' Operations

9. Defendants manufacture, sell, and distribute finished electronic nicotine delivery system ("ENDS") products at and from their Puyallup facility. Defendants' manufacturing activities include mixing, bottling, and labeling their ENDS products. Defendants also sell their ENDS

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products at their Lakewood and Spanaway facilities. Defendants sell and distribute their ENDS products to individuals for personal consumption.

Defendants' ENDS Products Are Adulterated and Misbranded

10. Defendants violate the Act by causing tobacco products to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce. 21 U.S.C. § 331(k).

Defendants' ENDS Products Are Tobacco Products.

11. The Act defines "tobacco product" at 21 U.S.C. § 321(rr) to include "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." A "tobacco product" within the meaning of 21 U.S.C. § 321(rr) is generally subject to the requirements in 21 U.S.C. ch. 9, subch. IX. See 21 U.S.C. § 387a(b) (providing that such subchapter shall apply to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that [FDA] by regulation deems to be subject to this subchapter"); 81 Fed. Reg. 28,974, 28,975 (May 10, 2016) (deeming all products meeting the definition of "tobacco product" at 21 U.S.C. § 321(rr), except accessories of such newly deemed products, to be subject to such subchapter).

12. ENDS products generally meet the definition of "tobacco product" at 21 U.S.C. § 321(rr), and include: "devices, components, and/or parts that deliver aerosolized e-liquid when inhaled." FDA, Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (Apr. 2020), 9–10, https://go.usa.gov/xuvn5. E liquids "are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids (i.e., liquid nicotine combined with colorings, flavorings, and/or other ingredients)." *Id.*

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13. Defendants' ENDS products are made or derived from tobacco, or contain nicotine from any source, and are intended for human consumption, and thus are "tobacco product[s]" within the meaning of 21 U.S.C. § 321(rr).

Defendants' ENDS Products Are New Tobacco Products.

14. The Act defines "new tobacco product" at 21 U.S.C. § 387j(a)(1) to include "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007."

15. Defendants' ENDS products were not commercially marketed in the United States as of February 15, 2007, and thus are "new tobacco product[s]" within the meaning of 21 U.S.C. § 387j(a)(1).

Pathways to Market for New Tobacco Products.

16. A new tobacco product may receive FDA marketing authorization through any one of three pathways: (1) the premarket tobacco product application ("PMTA") pathway under 21 U.S.C. § 387j, through which FDA reviews a PMTA and issues an order permitting marketing of the new tobacco product ("MGO") under 21 U.S.C. § 387j(c)(1)(A)(i) upon a finding that the product is appropriate for the protection of the public health; (2) the substantial equivalence ("SE") pathway under 21 U.S.C. § 387j(a)(2)(A)(i), through which FDA reviews a report submitted under 21 U.S.C. § 387e(j) ("SE report") for the product and issues an order determining, among other things, that it is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or a tobacco product marketed after that date, but which FDA previously determined to be substantially equivalent ("SE order"); or (3) the SE exemption pathway under 21 U.S.C. § 387j(a)(2)(A)(ii), through which FDA reviews an exemption request submitted under 21 C.F.R. § 1107.1 and a report submitted under 21 U.S.C. § 387e(j)(1) ("abbreviated report") for the product, and issues a "found-exempt" order pursuant to 21 U.S.C. § 387e(j)(3)(A).

17. A new tobacco product that is required by 21 U.S.C. § 387j(a) to have premarket review and does not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i), is adulterated under 21

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U.S.C. § 387b(6)(A). A new tobacco product is required by 21 U.S.C. § 387j(a) to have premarket review, unless it has an SE order or found-exempt order in effect. See 21 U.S.C. § 387j(a)(2)(A).

18. A new tobacco product for which a "notice or other information respecting it was not provided as required" under the SE or SE exemption pathway, including an SE report or an abbreviated report, is misbranded under 21 U.S.C. § 387c(a)(6).

Defendants' ENDS Products Have Not Been Authorized by FDA and Are Both Adulterated and Misbranded.

19. Defendants' ENDS products, as "new tobacco product[s]" within the meaning of 21 U.S.C. § 387j(a)(1), are required by 21 U.S.C. § 387j(a) to have premarket review, as they do not have an SE order or found-exempt order in effect. Defendants' ENDS products do not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i). Accordingly, Defendants' ENDS products are adulterated under 21 U.S.C. § 387b(6)(A).

20. In addition, neither an SE report nor an abbreviated report has been submitted for any of Defendants' ENDS products. Accordingly, Defendants' ENDS products are misbranded under 21 U.S.C. § 387c(a)(6).

Defendants Engage in Interstate Commerce.

21. Defendants hold their ENDS products for sale after shipment of their components in interstate commerce. Specifically, the flavors that Defendants use to make their ENDS products come from California and the nicotine comes from Arizona.

Defendants' History of Violative Conduct.

22. Defendants are aware that their practices violate the Act. FDA has warned Defendants about their violative conduct and explained that continued violations could lead to enforcement action, including an injunction.

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23. An FDA inspection conducted at Defendants' Puyallup facility on March 21, 2021, revealed that the company was manufacturing and offering for sale new tobacco products that lacked the required FDA authorization.

24. FDA sent the company and Defendant Marco Hoffman a Warning Letter on April 5, 2021, informing them that they manufacture and offer for sale or distribution new tobacco products that lack required FDA authorization. The Warning Letter identified one of their products that was sold without the required marketing authorization, SUPER VAPE'Z Premium E-liquid Apple Mango, 60ml 12mg, and explained that such product is adulterated under 21 U.S.C. § 387b(6)(A) and misbranded under 21 U.S.C. § 387c(a)(6). The Warning Letter further stated that "the violations discussed in this letter do not necessarily constitute an exhaustive list." The Warning Letter also noted that the company is registered with FDA as a tobacco products manufacturer with over 700 listed products and explained that it was their responsibility to ensure that their tobacco products comply with the law and failure to address their Act violations could lead to enforcement action, including an injunction.

25. On April 12, 2021, FDA received a written response from Mr. Hoffman. He stated that the company had "removed and discontinued the sale of . . . Apple Mango . . . on April 5, 2021."

26. On May 11, 2021, FDA responded and stated that the company had not adequately addressed the violation identified in the Warning Letter.

27. FDA and Mr. Hoffman had a teleconference on May 17, 2021, during which FDA explained that Super Vape'z Apple Mango was only an example of an unauthorized new tobacco product and that the Warning Letter applied to all of the company's unauthorized new tobacco products.

28. On April 4-7, 2022, FDA conducted a follow-up inspection at Defendants' Puyallup facility and found that Defendants continue to manufacture, sell, and distribute new tobacco products that lack required FDA authorization, in violation of the Act.

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Request for Relief

29. Despite prior notifications, Defendants remain unable or unwilling to comply with the Act. Unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing a violation of 21 U.S.C. § 331(k), by causing tobacco products to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce;

II. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to the manufacture, sale, and distribution of tobacco products, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

III. Award Plaintiff its costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Respectfully submitted,

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